AMERICAN PACIFIC CORPORATION

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January 21, 1999

Via Hand Delivery

The Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M Street SW, Room 1200
Washington, DC 20460

Subj: *Perchlorate Environmental Contamination: Toxicological Review And Risk Characterization Based on Emerging Information*, External Review Draft, December 31, 1998, (NCEA-1-0503)

Dear Ms. Browner:

This letter is with regard to the U.S. EPA document, *Perchlorate Environmental Contamination: Toxicological Review And Risk Characterization Based on Emerging Information* (NCEA-1-0503), published as an External Review Draft on December 31, 1998. This document purports to present information that is the basis for the derivation of a revised, oral reference dose (RfD) for perchlorate by the National Center for Environmental Assessment (NCEA). The aforementioned document is referred to hereafter in this letter as the External Review Draft.

American Pacific Corporation (AMPAC) is a manufacturer of perchlorate chemicals, one of which is an essential ingredient used as an oxidizer in solid rocket motor propellants used by NASA and DOD. Our company has an interest in ensuring that the RfD developed by EPA takes into consideration the best available data in humans and experimental animals. For that reason, we have been working with EPA and financially supporting studies to obtain independent scientific information about this issue.

We regret to have to bring to your attention some serious concerns regarding the External Review Draft and the process by which it is being considered. The first concern is the unreasonably short period of time allowed for submission of comments. The second concern is that the External Review Draft was released without accompanying unpublished references. The third concern is that the External Review Draft does not demonstrably consider prior human studies and reports that have been submitted to EPA. The fourth concern is that the External

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3770 HOWARD HUGHES PARKWAY • SUITE 300 • LAS VEGAS, NEVADA 89109
PHONE (702) 735-2200 • FAX (702) 735-4876

Review Draft was released prior to the completion of several ongoing, potentially important, experimental studies, including a perchlorate-exposure study in human volunteers. The fifth concern is that the analyses in the External Review Draft was based partly on a study ("2nd generation study") whose final report will not be published until the end of March.

No reasonable public review can be conducted within the current proposed time schedule. The External Review Draft is approximately two-hundred and fifty (250) pages long and contains one-hundred and eighty-six (186) references. Although the External Review Draft is dated December 31, 1998, it was not available to the general public until January 15, 1999, when it was posted on the Internet at the NCEA Web site. Those able to stop by (or send messengers to) NCEA's offices in Research Triangle Park, NC or Washington, DC were able to get copies of the document a few days earlier. The EPA deadline for submission of written comments on the External Review Draft (announced in the *Federal Register* of January 14, 1999) is February 1, approximately two weeks following the document's general release. As of this date, the references are not yet available to the general public and yet we are only 10 days away from the deadline for comments.

We were also informed on January 20 by EPA that for additional peer-reviewed studies to be fully considered or audited by EPA prior to the February 10th meeting, they must be received by January 22, 1999. It is our understanding that EPA's rationale for these deadlines is that comments and additional data must be received in time to be reviewed by the external peer-reviewers prior to the external peer-review workshop scheduled for February 10-11 in San Bernardino, CA. Regardless of the rationale for the February 1 deadline, we believe that the time allotted for review of the External Review Draft is too short. It is unreasonable for EPA to expect that interested parties will have sufficient time to review the External Review Draft and prepare a written critique by February 1.

Moreover, the public has not had any opportunity to review many of the studies and documents on which the External Review Document is based. Many of the references in the External Review Document cite unpublished material, including internal communications, documents developed in support of the External Review Draft, and final or interim reports from the five new, animal-toxicity studies upon which NCEA based the derivation of the revised RfD. Without access to the complete text of these materials, it is virtually impossible to conduct an adequate scientific review of the External Review Draft. Through the Freedom of Information Act, we have requested that EPA supply copies of all unpublished materials cited in the External Review Draft (see attached). Even if all such materials are supplied immediately and in their entirety as requested, we do not expect that a scientific review can be completed by the deadline of February 1 or even by the time of the external peer-review workshop on February 10-11.

The External Review Draft states, "The target tissue for systemic effects of perchlorate is the thyroid", and "The revised RfD is based on an assessment that reviewed a set of studies that were developed to explicitly evaluate these potential toxicities." Summaries of the results of these new toxicity studies appear in the External Review Draft; this is the only way thus far that the data have been made available to interested members of the general public. According to our best information, it is highly unusual for EPA to derive an RfD based on studies which have been neither published nor made available in any form to the general public. We have difficulty understanding why the reports describing the new toxicity studies were not released earlier; certainly there has been sufficient opportunity to do so. The public should have been given a reasonable opportunity to review and comment upon the study reports before they were used in the development of any proposed regulatory value. Considering that the studies were funded partially with federal money,[1] it becomes even more puzzling why the study reports were not released into the public domain at the same time they became available to EPA.

The great "rush to judgment" caused by the unreasonably brief period for public review, and the absolute inability of the public to even read key underlying studies is serious enough. But as a matter of science, the fact that the External Review Document relies primarily on animal studies is nearly incomprehensible, when data from human studies is available and more human studies are underway. A fair amount of data on safe levels of human exposure to perchlorate has been reported in the literature, including observational studies in patients treated with perchlorate to control thyroid dysfunction, occupational health studies in perchlorate workers, and at least one perchlorate-exposure study in human volunteers. It appears that none of the human studies was considered by NCEA, despite the fact that these could be of importance to the development of a scientifically defensible RfD. We recognize that science on an issue is never complete, and that there is always going to be additional data offered; however, in this case EPA has stated that there was a minimum set of eight studies which were required for derivation of an RfD. Two of those studies (the "2nd Generation Study" and the "Immunotoxicity Study in Mice") will not be completed until March and June, respectively.

Another perchlorate-exposure study in human volunteers is in progress; this is being conducted by Dr. Lewis E. Braverman, Visiting Professor of Medicine at Harvard Medical School, a well-regarded expert on the human thyroid. The study protocol (The Effect of Low Dose Perchlorate on Thyroid Function) has been approved by the Human Research Committee of Brigham and Women's Hospital (a teaching affiliate of Harvard Medical School). In addition, while not a federally funded study or intended for submission for a pharmaceutical concern, the study complies with all relevant common policy published by the Department of Health and Human Services. The study is designed to examine the effects of perchlorate on thyroidal

iodide uptake and serum levels of thyroid hormones at perchlorate doses considerably lower than those tested to date. We believe that the results of this study should be considered by EPA before a revised RfD for perchlorate is finalized and published in IRIS.

In addition, the Air Force Research Laboratory (AFRL) is currently conducting single-dose and 14-day exposure studies of the kinetics of perchlorate inhibition of thyroidal iodide uptake in rats. Clearly, EPA is aware of these studies through its membership in the Interagency Perchlorate Steering Committee (IPSC), if not through other means. The data-gathering phases of the AFRL study in rats and the Braverman study in humans are expected to be complete by the end of February.

In the interest of allowing a reasonable and scientific review of the information contained in NCEA-1-0503, we hereby request that the date of the external peer-review workshop now scheduled for February 10-11 be postponed by at least 90 days (and the February 1 deadline for written comments to be fully considered likewise postponed by at least 90 days) on the basis of the following:

1. Lack of provision of a reasonable amount of time to review the NCEA External Review Draft Report and its 186 references;
2. Failure to provide timely access to unpublished sources relied on in the External Review Draft;
3. Importance of inclusion of the results of the Braverman human-exposure study and the AFRL rat study in the external-review process so that an assessment of all potentially important, toxicological information can be accomplished;
4. Analyses in the External Review Draft was made on the basis of a study ("2nd generation study") that is not yet complete; and
5. No consideration of prior human studies and reports submitted to EPA.

Any one of these deficiencies would warrant an extension. Taken together, they compel one. Accordingly, we would appreciate your prompt consideration of the points made above. Please note that our request for a 90-day postponement of the external peer-review workshop (and the deadline for comments) is conditioned upon our receiving, within two weeks of the date of this letter, copies of the complete text of all references in the External Review Draft that we have requested under the Freedom of Information Act. If it takes EPA longer than two weeks to supply us with the reports and other materials, we will formally request that the postponement be lengthened accordingly.

We believe that only if there is adequate time for review, full access to information relied on by EPA, and use of the best scientific information will the interest of the public be served and the requirements of the law respected.

Sincerely,

John R. Gibson
Chairman, President, and C.E.O.

JRG/j
Enc.

cc: Ms. Norine E. Noonan, Ph.D.
Assistant Administrator
Office of Research and Development
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

William H. Farland, Ph.D.
Director
National Center for Environmental Assessment
U.S. Environmental Protection Agency
401 M Street, SW (8601)
Washington, DC 20460

Mr. Timothy Fields, Jr.
Acting Assistant Administrator
Office of Solid Waste and Emergency Response
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Notes

1 "Funding for the studies was procured and obligated through a variety of sources, principally the USAF and the Perchlorate Study Group (PSG)." Source: US EPA Office of Ground Water and Drinking Water, Web address: www.epa.gov/ogwdw/ccl/perchlor/perchlo.html.

From: GIRARD, MICHAEL F <Michael.Girard@Aerojet.com>
To: 'Dorothy Canter' <canter.dorothy@epamail.epa.gov>
Date: 1/22/99 12:22pm
Subject: Perchlorate External Peer Review

Dear Dorothy,

On behalf of the Perchlorate Study Group I wanted to express our collective concern regarding the upcoming perchlorate external peer review. While the PSG recognizes the teams original goals and commitments to schedule the external peer review in February, we now are concerned that this objective may not be in the best interest of all the parties involved. It is the consensus of the PSG that to enable the external peer review panel members to make the best scientific recommendations to NCEA, they should posses all available scientific information regarding perchlorate health effects and have adequate time to review that data. The PSG also believes that the EPA decision to allow the stakeholders an opportunity to participate in this process was a sound decision that should be commended. Unfortunately the current time schedule does not allow adequate time for stakeholders to review the data, request back-up documentation and prepare a response. The external peer review panel will also not be afforded much time to review the additional comments before the peer review.

It is the recommendation of the PSG that;

1) The external peer review panel have in their possession of all available data including the final reports on immunotox and the two generation study.
2) Consideration be given to postponing the external peer review until such time as NCEA has the opportunity to incorporate these two remaining final studies.
3) Adequate time is afforded to NCEA and other stakeholders in presenting information to the panel.
4) The peer review panel have additional time to review the documentation relevant to perchlorate health effects prior to the peer review.

I would like to conclude by saying that this has been a extraordinary effort by a team of individuals and agencies in responding to the public issue of perchlorate. We truly appreciate the EPA's dedication and involvement in this process and being given the opportunity to participate.

Michael Girard

Chairman
Perchlorate Study Group
Bldg 20019 / Dept 0330
P.O. Box 13222
Sacramento, CA 95813-6000

916.355.2945
916.355.6145 Fax
michael.girard@aerojet.com

CC: 'William Farland' <farland.william@epamail.epa.gov...

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RENO OFFICE
400 S. Virginia Street
Suite 702
Reno, NV 89501
(702) 686-5770

Las Vegas Boulevard South
Suite 1110
Las Vegas, NV 89101
(702) 388-6605

East William Street
Suite 304
Carson City, NV 89701
(702) 885-3111

United States Senate

269 RUSSELL SENATE OFFICE BUILDING
WASHINGTON, DC 20510-2804
(202) 224-6244

January 28, 1999

The Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M Street, SW
Washington, D.C. 20460

Dear Administrator Browner:

It is my understanding that on February 10, 1999, the EPA will hold a "technical workshop on perchlorate risk issues" in San Bernardino, California, in order to allow the public and other interested parties to review information that is the basis for a revised oral reference dose (RfD) for perchlorate. Information for this review is contained in a report by the National Center for Environmental Assessment entitled, "Perchlorate Environmental Contamination: Toxicological Review and Risk Characterization Based on Emerging Information," published on December 31, 1998.

I further understand that the main report to be discussed during this meeting was not made available to the public until mid-January, and that most of the 186 documents used as references in the report are not readily available for public review. Additionally, several studies that the EPA previously deemed necessary in order to derive a proper perchlorate RfD have not yet been completed. A 90-day postponement of this meeting would allow for proper review of the documents, completion of important studies, and adequate time for public review and comments.

I appreciate your consideration of this request.

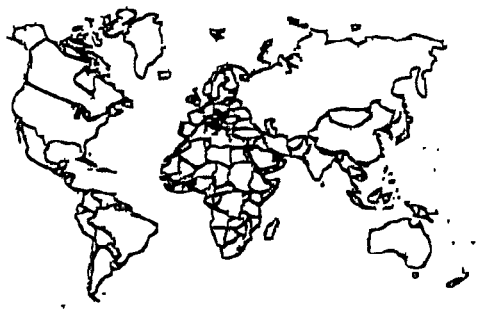
Sincerely,

Richard H. Bryan
United States Senator

cc: Timothy Fields, Jr., Acting Assistant Administrator
Office of Solid Waste and Emergency Response

ENVIRONMENTAL PROTECTION AGENCY
Office of Solid Waste and Emergency Response

Fax number: (202) 260-3527



To: Catherine McCracken Fax Number: 415-744-1796

Date: 1/28/99 Pages (including this cover sheet): 9

From: Drinking Center Office number: 202-260-2230

Subject: Request to Delay of Peer Review of Perchlorate Toxicity (3)

COMMENTS